





PATENT ORNEY DOCKET NO. 50195/008003

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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

James M. Robl et al.

Art Unit:

1632

Serial No.:

09/988,115

Examiner:

D. Crouch

Filed:

November 16, 2001

Customer No.:

21559

Title:

TRANSGENIC BOVINE COMPRISING HUMAN

IMMUNOGLOBULIN LOCI AND PRODUCING HUMAN

**IMMUNOGLOBULIN** 

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

### PETITION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

Applicants petition for reconsideration of the Decision on Application for Patent Term Adjustment mailed June 7, 2006 in connection with the above-captioned patent application. Applicants agree that the current patent term adjustment should be 0 days. Nonetheless, to preserve their right to recapture the full amount of patent term calculated at the time of patent issuance, Applicants request reconsideration on delay attributed to Applicants during pre-issuance prosecution. The correct calculation of Applicant delay is 262 days, not 323 days as determined by the Office.

Following consideration of the Office's Decision, it is agreed that Applicant delay occurred in connection with four submissions: a Reply to Notice of Missing Parts of December 4, 2001 submitted on June 6, 2002, a delay of 94 days; an Information Disclosure Statement submitted June 9, 2004, a delay of 58 days; a Reply to a non-final Office Action of July 29, 2004 submitted on January 31, 2005, a delay of 94 days; and a Reply to a final Office Action of April 20, 2005 submitted on August 5, 2005, a delay of 16 days. This results in a total Applicant delay of 262 days.

Applicants continue to take issue with the Office's assessment of Applicant delay in connection with the timely submission of a sequence listing and sequence diskette on February 7, 2002, in response to a Notice to File Missing Parts mailed December 4, 2001. As previously indicated, this submission was date-stamped as received and complete by the PTO on March 11, 2002 (copy of postcard previously enclosed). On June 24, 2002, Applicants were informed, through the mailing of a further Notice to Comply with Sequence Listing Requirements, that Applicants' sequence diskette was "Damaged." Applicants previously submitted that this damage resulted from security procedures at the PTO and was not the result of Applicant error or delay. The Office has dismissed this argument, stating:

Applicants argument has been considered but is not found convincing. The Notice to Comply with Sequence Listing Requirements indicated that applicants' diskette was damaged and/or unreadable. There is no indication in the official record that any damage to the disk or unreadability of the disk is attributable to any action or inaction on the part of the Office. Accordingly, the submission of the reply on August 6, 2002 is deemed a failure to engage in reasonable efforts to conclude prosecution with in the meaning of 37 CFR 1.704(c)(7).

Applicants take issue with this position. First, the Notice to Comply does not · indicate that "applicants' diskette was damaged and/or unreadable." Rather, it clearly indicates that the diskette was "Damaged," as shown by the enclosed copy of the CRF Problem Report. This is consistent with damage due to security measures. Second, the problem with the diskette occurred shortly after security procedures were instituted by the Patent Office following September 11, 2001, a time period when damage to diskettes due to security procedures was common. Third, as indicated by the accompanying Declaration, Applicants' counsel retained, in their files, a copy of the original sequence diskette mailed to the U.S. Patent Office on February 7, 2002. This diskette has been checked and shown to be undamaged and readable. Thus, Applicants submit that all available evidence indicates that the diskette timely mailed by Applicants was in full compliance with the sequence rules and that damage to the diskette occurred after its receipt by the Patent Office. Moreover, to Applicants' knowledge, the "official record" of the Patent Office is silent on the question of whether Applicants' diskette arrived damaged. All that is indicated by the record is that, following security measures, the damage to the diskette was noted. Applicants submit that this does not support the Office's contention that damage to the diskette was attributable to Applicants; nor should it support a reduction in Applicants' patent term. Reconsideration on this portion of the decision is requested, as is issuance of a revised Decision on Application for Patent Term Adjustment.

If there are charges or any credits in connection with this submission, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 19 Grene 200 6

Karen L. Elbing, Ph.

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Telephone: 617-428-0200 Facsimile: 617-428-7045







#### **PATENT** ATTORNEY DOCKET NO. 50195/008003

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#### DECLARATION OF KAREN L. ELBING

#### I declare:

- 1. I am patent counsel representing the above-captioned Applicants.
- 2. On behalf of Applicants, our office submitted a sequence diskette on February 7, 2002 (date-stamped received by the PTO on March 11, 2002) in response to a Notice to File Missing Parts mailed December 4, 2001. A copy of the submitted sequence diskette was retained in our file.
  - 3. We have checked our file copy of the sequence diskette. The diskette is

undamaged and readable.

4. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

19 June 2006

Date

Clark & Elbing LLP 101 Federal Street

Boston, MA 02110

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BIOTECHNOLOGY TEMS PRANCH

## CRF Problem Report

The Scientific and Technical Information Center (STIC) experienced a problem when processing the following computer readable form (CRF):

Application Serial Number: 09 988 115
Filing Date: 11 160
Date Processed by STIC: 322102

STIC Contact: Mark Spencer, 703-308-4212

### Nature of Problem:

The CR	F (was):
	ircle one) Damaged or Unreadable (for Unreadable, see attached) lank (no files on CRF) (see attached)
Er	mpty file (filename present, but no bytes in file) (see attached)
v ;	irus-infected. Virus name: The STIC will not process the CRF
Se	equence Listing was embedded in the file. According to Sequence Rules, submitted file should only be the Sequence Listing
D	and not contain a Sequence Listing. (see attached sample)
Se	equence Listing was embedded in the file. According to Sequence Rules, submitted file should only be the Sequence Listing.

# PLEASE USE THE CHECKER VERSION 3.1 PROGRAM TO REDUCE ERRORS. SEE BELOW FOR ADDRESS:

http:/www.uspto.gov/web/offices/pac/checker

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

- 1. EFS-Bio (<a href="http://www.uspto.gov/ebc/efs/downloads/documents.htm">http://www.uspto.gov/ebc/efs/downloads/documents.htm</a>, EFS Submission User Manual ePAVE)
- 2. U.S. Postal Service: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
- 3. Hand Carry directly to:

  U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7th Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202
  - U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
- Federal Express, United Parcel Service, or other delivery service to: U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

Revised 01/29/2002